

Message Text

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ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 PASS-00 /025 W
-----211949Z 000340 /47

R 211615Z JAN 77
FM AMEMBASSY ROME
TO SECSTATE WASHDC 2295

UNCLAS SECTION 1 OF 2 ROME 1032

E.O. 11652: N/A
TAGS: SWEL, IT
SUBJ: PRESENTATION OF PAPER

DEPT PASS TO PROF. FRANK GROSS, PRINCESS KAIULANI HOTEL, 120
KAIULANI AVENUE, HONOLULU, HAWAI

PROFESSOR DULIO POGGIOLINI, DIRECTOR GENERAL OF PHARMACEUTICS,
ITALIAN MINISTRY OF HEALTH, UNABLE TO PRESENT HIS PAPER AND
THEREFORE REQUESTS THAT YOU HAVE IT READ FOR HIM. THE PAPER
FOLLOWS:

QTE. INTERNATIONAL CONSULTATIONS ON DECISIONS TO BE TAKEN IN
CASE OF UNTOWARD SIDE EFFECTS OF DRUGS.
PHARMACOLOGY DEVELOPMENT HAS TAKEN ON, THESE LAST THREE DECADES,
STRIKING FEATURES OWING TO THE IMPORTANCE OF THERAPEUTICAL
ACHIEVEMENTS AS WELL AS TO THE SCIENTIFIC VALUE OF THE PROGRESS
ATTAINED. THIS PROGRESS REPRESENTED A FURTHER STIMULUS FOR
SCIENTIFIC DEVELOPMENT IN THE FIELDS OF CHEMISTRY, PHYSIOLOGY
AND PATHOLOGY. IT IS THEREFORE UNDOUBTED AND UNIVERSALLY
RECOGNIZED THAT PHARMACOLOGICAL PROGRESS HAS BROUGHT ABOUT
ENORMOUS BENEFITS TO LIFE OF MAN, ACHIEVING ALSO EXTREMELY
IMPORTANT SOCIAL IMPROVEMENTS. HOWEVER AS ACCORDING TO A NATURAL
LAW - NO ADVANTAGE CAN BE OBTAINED WITHOUT A COST TO BE PAID,
ALSO IN THIS FIELD AN ALWAYS GREATER ATTENTION IS BEING DRAWN
UPON RISKS AND DAMAGES DERIVING FROM THE USE OF DRUGS.
THESE RISKS, WHY DO THEY BECOME EVERY YEAR MORE EVIDENT?

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AND WHY DOES PUBLIC CONCERN ON THIS MATTER BECAME INCREASINGLY
ALIVE? IN THIS BRIEF REPORT I WILL TRY TO ANALYZE THIS PHENOMENON
AND BETTER SPOT ITS CAUSES. JUST TO BEGIN, IT HAS TO BE OBSERVED
THAT THE FIRST REMARKABLE THERAPEUTICAL REALIZATIONS (USE OF THE
FIRST ANTIBIOTICS, CORTICOSTEROIDS, DIURETICS, ANTIDIABETICS,
ETC.) HAVE BROUGHT ABOUT SO MANY BENEFITS IN THE STRUGGLE AGAINST
DISEASE, THAT THE SIDE EFFECTS INEVITABLY CONNECTED WITH THEIR

USE WERE NOT TAKEN INTO DUE CONSIDERATION; THEY WERE, ON THE CONTRARY, EVEN EASILY ACCEPTED. SUBSEQUENTLY, OWING TO THE ATTAINMENT OF BETTER HEALTH CONDITIONS FOR THE WHOLE POPULATION, AS WELL AS TO THE SOMETIMES INDISCRIMINATED INCREASING OF THE USE OF DRUGS WHICH OCCURED SIMULTANEOUSLY, VARIOUS KINDS OF EFFECTS OF THESE PRODUCTS HAVE BECOME THEMSELVES THE CAUSE OF AN ALTERATION OF THE PSYCHO-PHYSICAL WELL-BEING AND ARE NOW THEREFORE THE OBJECT OF OBSERVATION AND INTEREST. ON THE OTHER HAND, THE ALWAYS GREATER EVIDENCE OF SIDE EFFECTS OF DRUGS DOES NOT ONLY DEPEND ON THEIR BETTER IDENTIFICATION, BUT ALSO ON A SUBSTANTIAL INCREASE IN THEIR NUMBER. THE CAUSE OF THIS PHENOMENON IS TO BE FOUND IN THE TYPE OF PHARMACOLOGICAL DEVELOPMENT WHICH HAS TAKEN PLACE IN THESE LAST YEARS FOLLOWING THE FIRST MAJOR THERAPEUTIC REALIZATIONS. IN MORE RECENT YEARS WE HAVE IN FACT OBSERVED THAT PHARMACOTHERAPEUTIC RESEARCH IS PROCEEDING ACCORDING TO FIXED SCHEMES, CLOSELY RESEMBLING ONE ANOTHER. THIS IS DUE TO THE FEW INNOVATIONS IN THE RESEARCH SYSTEMS, BUT ALSO, AND ABOVE ALL, TO THE CONDITIONING OF RESEARCH BY FIRMS AND COMMERCIAL INTERESTS, AND PARTICULARLY BY THE MARKETING PRESSURE. WE ARE THEREFORE WITNESSING THE ENDLESS REPETITION BY VARIOUS PHARMACEUTICAL FIRMS OF COMPOUNDS EXREMELY SIMILAR IN THEIR STRUCTURE AND PHARMACOLOGICAL ASPECTS, WICH THUS DO NOT SHOW ANY PARTICULAR BENEFIT, BUT ON THE CONTRARY OFTEN PRESENT RELEVANT SIDE EFFECTS. BEARING IN MIND THE PRESENT SITUATION IT IS THEREFORE QUITE PROBABLE THAT FOR A CERTAIN TIME - THE DURATION OF WHICH CANNOT YET BE FORESEEN - DRUGS SCARCELY DIFFERENTIATED AS REGARDS BOTH THEIR ACTIVITIES AND PROPERTIES, AND PERHAPS NOT DEVOID OF RATHER NOTICEABLE SIDE EFFECTS, WILL BE PUT ON THE MARKET. FROM WHAT I HAVE PREVIOUSLY UNCLASSIFIED

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STATED, IT APPEARS OBVIOUS THAT THE PROBLEM OF THE SIDE EFFECTS OF DRUGS HAS TAKEN TODAY A GREAT IMPORTANCE, WHICH COULD STILL BE GREATER IN THE FUTURE. ON THE BASIS OF OUR PREVIOUS EXPERIENCE IT IS HOWEVER NECESSARY TO LOOK FOR NEW ASPECTS OF THIS PROBLEM. I FEEL THAT IN A SOCIETY WHICH - IN ALL ITS COMPONENTS, INCLUDING THE LEGAL ONES - IS SO DEEPLY SENSITIVE TO ALL THE PROBLEMS CONNECTED WITH THE USE OF DRUGS, IT IS IN THE VERY INTEREST OF NATIONAL REGULATORY AUTHORITIES TO DETECT SOONEST POSSIBLE THOSE SIDE EFFECTS WHICH A LARGE DIFFUSION OF NEW PRODUCTS COULD LATER REVEAL AND TO TAKE ALL THE CONSEQUENT NECESSARY MEASURES. TO REACH THIS END, A RELATION OF MUTUAL TRUST AMONG THE INTERESTED NATIONAL AGENCIES IS IMPERATIVE AS IT IS EVIDENT THAT, ON ACCOUNT OF THE PARTICULAR SENSITIVENESS OF PUBLIC OPINION ON DRUG MATTERS, ANY ACCIDENT IN THIS SECTOR MIGHT CAUSE A SERIOUS DAMAGE FOR THE ADMINISTRATIONS. THE SELECTION OF DATA AND THE CERTAINTY OF THEIR INTERPRETATION ARE THEREFORE OF PARAMOUNT IMPORTANCE AS REGARDS MEASURES TO BE TAKEN. I FEEL THEREFORE NECESSARY TO SET FORTH SOME IDEAS ON THE PROBLEM, WHICH TODAY WE CONSIDER STILL MORE IMPORTANT, OF

THE COORDINATION OF THE VARIOUS AGENCIES CONCERNED AS REGARDS
THIS SECTOR. THE NEED OF A COORDINATION OF THE OPERATIVE DECISIONS
TO BE TAKEN FOLLOWING THE INDICATION OF UNDESIRABLE SIDE EFFECTS
APPEARS MORE EVIDENT, EVEN IF CONTINGENT, AND BACKGROUND
SITUATIONS ARE DIFFERENT. IT IS IN FACT QUITE EASY TO OBSERVE
THAT HEALTH INTERESTS ARE COMMON TO EVERY COUNTRY AND THAT THE
USE OF DRUGS, ON THE BASIS OF SIMILAR REGULATIONS,
TENDS TO PROPAGATE IN DIFFERENT COUNTRIES WHICH, THEREFORE, ARE
BECOMING ALL DIRECTLY INTERESTED IN THE EFFECTS OF THE SAME
ACTIVE PRINCIPLE.
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ACTION HEW-06

INFO OCT-01 EUR-12 ISO-00 OES-06 PASS-00 /025 W
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R 211615Z JAN 77
FM AMEMBASSY ROME
TO SECSTATE WASHDC 2296

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FURTHERMORE, IT HAS TO BE REMEMBERED THAT PUBLIC OPINION DOES
NOT TOLERATE A DIFFERENT POLICY BY THE VARIOUS NATIONAL AUTHORITIES;
IT IS THEREFORE OBVIOUS THAT, PARTICULARLY IN OUR MODERN WORLD
WHERE NEWS CIRCULATE SO RAPIDLY, PARTITION WALLS AMONG THE
VARIOUS COUNTRIES ARE NO MORE POSSIBLE AND THERE IS NO EXCUSE
FOR THE PHARMACEUTICAL INDUSTRY TO APPEAL - NOW AS IT DID IN
THE PAST - TO RESERVENESS BETWEEN COUNTRY AND COUNTRY. IT
IS QUITE OBVIOUS THAT, SHOULD AN AUTHORITY KEEP A DECISION
HIDDEN, EVEN WORSE CONSEQUENCES MIGHT ARISE. A LAST POINT
IS THAT WE MUST NOT UNDERESTIMATE THAT, IN A MATTER SO DELICATE
AND OFTEN PERMEATED WITH COMPLEX MOTIVATIONS, DECISIONS TAKEN
IN COMMON ARE MORE EASILY FREE FROM SECTORIAL AND NOT STRICTLY
SCIENTIFIC INFLUENCES. THE COORDINATION AMONG NATIONAL
AGENCIES HAS TO BE BASED ON A TWOFOLD TYPE OF INFORMATION:

1. A RECIPROCAL CONSULTATION ON THE NATURE AND IMPORTANCE
OF THE ASCERTAINED EFFECTS;
2. A RECIPROCAL CONSULTATION ON THE DECISIONS TO BE TAKEN
ACCORDINGLY. AS REGARDS POINT 1), THE RECOMMENDATIONS EXPRESSED

AT WHO'S MEETING "TRANSFER OF INFORMATION RELATING TO DRUGS AND THEIR REGISTRATION" (GENEVA, SEPTEMBER 28-OCTOBER 2, 1976) APPEAR TO BE PARTICULARLY INTERESTING. IN THIS CONTEXT, STRESS HAS BEEN LAID UPON THE ADVISABILITY OF CONSTANT INFORMATION AMONG THE NATIONAL REGULATORY AUTHORITIES ON: PENDING APPLICATIONS, REFUSED APPLICATIONS, RECENTLY REGISTERED PRODUCTS, ESTABLISHED PRODUCTS, SUSPECTED ADVERSE REACTIONS, SPECIFIC REGULATORY ACTION TAKEN ON CONSIDERATION OF SAFETY. THE BASIS FOR THE UNCLASSIFIED

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EVALUATION BY EACH NATIONAL REGULATORY AUTHORITY IS THE RECIPROCAL CONTINUOUS INFORMATION ON THE ABOVE SUBJECTS. HOWEVER, ALSO A CONSULTATION AMONG THE VARIOUS NATIONAL AGENCIES ON THE MEASURES TO BE TAKEN AS TO THE SAFETY OF DRUGS, APPEARS TO BE CONVENIENT AND, SOMETIMES, NECESSARY. THEY COULD CONSIST OF (IN ORDER OF SEVERITY):

1. INTRODUCTION OF SUITABLE LIMITATIONS AND CONTROLS ON THE USE OF DRUGS;
2. ELIMINATION OF ONE OR MORE COMPONENTS (ACTIVE PRINCIPLES, ECCIPIENTS, COLORING MATTERS, ETC.) FROM THE PRODUCT;
3. WITHDRAWAL FROM THE MARKET OF THE PRODUCT. THE CONSULTATIONS AMONG AGENCIES COULD TAKE PLACE THROUGH:

1. EXCHANGE OF IDEAS OR BILATERAL MEETINGS IF THE PROBLEM CONCERNS MORE CLOSELY TWO COUNTRIES;
2. MULTILATERAL MEETINGS WHEN THE PROBLEM IS OF COMMON INTEREST FOR MANY COUNTRIES.

THE NECESSITY OF SUCH AN INITIATIVE APPEARS QUITE OBVIOUS. IT IS IN FACT POSSIBLE THAT DECISIONS TAKEN BY A SINGLE COUNTRY ON PARTICULAR LIMITATIONS IN THE USE OF DRUGS (SUCH AS WARNINGS, CONCTRAINDICATIONS, ETC.), OR ORDERS FOR MODIFICATIONS IN THE COMPOSITION OF CERTAIN DRUGS FOR ONE OR MORE OF THEIR COMPONENTS, PRESERVATIVES OR ECCIPIENTS, MAY HINDER THE ESTABLISHMENT OF EQUIVALENT HEALTH LEVELS, IN CASE SIMILAR MEASURES ARE NOT TAKEN BY OTHER COUNTRIES WHERE THE SAME DRUG IS ON THE MARKET AND IN WHICH THERE ARE THE SAME ENVIRONMENT AND BIOLOGICAL SUSCEPTIBILITY RACIAL CONDITIONS. THIS INITIATIVE, HOWEVER, MUST SUITABLY DEVELOP AND, FROM A SIMPLE EXCHANGE OF IDEAS AND INFORMATION, GROW INTO A REAL COMMON TECHNICAL CONSULTATION AND EVALUATION. THE USEFULNESS OF SUCH A SERVICE IS QUOTE CLEAR: DATA OFTEN CONTROVERSIAL AND UNCERTAIN, COULD BE THE OBJECT OF A SCIENTIFIC EVALUATION WHICH WOULD CONSIDER ALL THE DIFFERENT EXPERIENCES; CONCLUSIONS MIGHT THUS BE REACHED MUCH MORE RAPIDLY AND WOULD HAVE SUCH AND ENLARGED BASIS AS TO MAKE ALSO MORE QUICK, UNCLASSIFIED

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SURE AND EFFICIENT THE OPERATIVE DECISIONS OF BOTH NATIONAL AND
SUPER-NATIONAL INTERESTED AGENCIES.VOLPE

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Message Attributes

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Disposition Approved on Date:
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Executive Order: N/A
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Office: ACTION HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
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Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
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Review Action: RELEASED, APPROVED
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Review Media Identifier:
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
SAS ID: 3534885
Secure: OPEN
Status: NATIVE
Subject: PRESENTATION OF PAPER DEPT PASS TO PROF. FRANK GROSS, PRINCESS KAIULANI HOTEL, 120 KAIULANI AVENUE, HONOLULU, HAWAI
TAGS: SWEL, IT, US, (GROSS, FRANK), (POGGIOLIN, DULIO)
To: STATE
Type: TE
vdkgvwkey: odbc://SAS/SAS.dbo.SAS_Docs/4fd4b7d2-c288-dd11-92da-001cc4696bcc
Review Markings:
Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
22 May 2009
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009